K002781

MEDICAL CABLES™

NOV 2 9 2000

1340 LOGAN AVENUE, COSTA MESA, CA 92626•(714) 545-3469•(800) 828-1599•FAX (714) 545-7212

510(k) Summary

Contact Person: Robert Hilman, Quality / Regulatory Affairs
1340 Logan Avenue
Costa Mesa, CA 92626
Phone : 1 (800) 828 1599 Fax : 1 (714) 545 7212

Date Prepared: August 28th, 2000

Product Classification: Class II Cardiovascular 74 DSA, 21 CFR 870.2900
Patient Monitoring Cables for ECG, EEG, SpO2 and Blood Pressure Monitors.

Trade Name: Medical Cables Patient Monitoring Cables for ECG, EEG, SpO2 and Blood Pressure Monitors.

Common Name: Various Patient Monitoring Cables and Lead Wires.

Predicate device: These devices are equivalent to the following legally marketed devices manufactured by

- KENDALL Corporation,
  (Tronomate 510(k) number K952659)
- Merit Industries, 510(k) number K942321

Description: Medical Cables' most common cable lead wire configuration ECG Cable is of various lengths of purchased specified color coded lead wire that is terminated at one end into a similarly colored injection molded DIN .062 " socket and at the other end into a similarly colored injection molded snap on connector. When in use the DIN .062" socket is attached to a similarly colored outlet at the yoke from the cable to the monitor and the snap on connector is attached to the sensor electrode on the patient.

Intended Use: Medical Cables Cables and Lead wires are used with ECG's, EEG's, SpO2's and Blood Pressure Monitors and are solely intended to be used between the electrode in contact with the patient i.e. appropriate suction cup, pad, clip, sensor or other specific means and the monitoring device. This protected cable or lead connection facilitates the conduction of signals between the patient and the monitoring device.

Performance Standard ANSI/AAMI EC53 –1995
FDA 21 CFR Part 898 Final rule [Docket No: 94N-0078]

Manufacturing Facility: Medical Cables distributes and manufactures various Patient Monitoring Cables and Lead wires used with ECG's, EEG's, SpO2's and Blood Pressure Monitors under FDA Device Establishment Number 2030533 and Owner Operator Number 9011649. Medical Manufacturing produces the ECG cable for Medical Cables.

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MEDICAL CABLES PRODUCT COMPARISON TABLE TO PREDICATE DEVICES

	Medical Cables	KENDALL Corporation	Merit Industries
Only intended use	To facilitate conduction of impulse from the sensor to the monitor.	Same	Same
Patient usage	Reusable	Same	Same
Anatomical Sites	Attached to sensors placed at Standard Specified locations on chest wall	Same	Same
Design / Appearance	Colored Cable with DIN & snap on connector and various other connectors.	Same	Same
Design of Pin and Socket Terminals / Connector	Various Connectors.	Same	Same
Cable Length	Various Specified Standard Lengths	Same	Same
Wire color	Multi-colored e.g. red, white, green, blue, black, white, brown, orange, or other.	Same	Same
Wire Material	Tin Copper / PVC jacket.	Same	Same
Sterility	Used Non Sterile.	Same	Same
Electrical performance Testing Results	Standard 5 lead graph produced with Tester	Same	Same
Electrical Safety Testing Supplier Standard Test	Dielectric Withstanding Voltage 1.0 KVAC	Same	Same
Electrical Safety Testing Supplier Standard Test	Insulation Resistance – 1000 megohms minimum initial .	Same	Same
Electrical Safety Testing Supplier Standard Test	Termination resistance – specified current / milliohms.	Same	Same
Connector retention force 4.5.9.1 ANSI/AAMI EC53A-1998 (Amendment)	Pulling axially along direction of Lead Wire connected to the trunk cable yoke with a minimum force of not less than 1 lb. The connector should not separate.	Same	Same
Environmental Safety Supplier Standard Test	Temperature rise at rated current	Same	Same
Meets requirements of ANSI/AAMI Standard.	ANSI/AAMI EC53-1995	Same	Same

CONCLUSION : As described in tabulated section 9.1, Medical Cables has demonstrated conformity and substantial equivalence of product to the following predicate devices manufacturers :

Predicate Manufacturer	Predicate Device	510(k) Number
KENDALL – (Tronomed)	Tronomate Patient Cable and Leadwire Systems	K952659
MERIT INDUSTRIES	Various Patient Monitoring Cables	K942321

This 510(k) summary of safety and effectiveness information of product is submitted in accordance with the requirement of 21 CFR § 807.92(c).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 2 9 2000

Mr. Robert Hilman
Quality and Regulatory Affairs
Medical Cables™
1340 Logan Avenue
Costa Mesa, CA 92626

Re: K002781
Trade Name: Medical Cables Patient Monitoring Cables for ECG, EEG, SpO2 and Blood Pressure Monitors
Regulatory Class: II (two)
Product Code: DSA
Dated: August 30, 2000
Received: September 6, 2000

Dear Mr. Hilman:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition,

FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

his letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4248. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

James E. Dillard III
Director
Division of Cardiovascular and
Respiratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

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STATEMENT OF INDICATIONS FOR USE

Medical Cables EKG Cables and Leadwires are used with ECG's for diagnostic and monitoring purposes by qualified personnel in the field of Cardiology for both Normal and Pathologic conditions. The function of Medical Cables and Leadwires is solely to provide a connection for signals to pass through from the patient to the Monitoring or Recording Device. No other usage is intended for the Cables or Leadwires.

Christopher Fontana

30th August, 2000

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K002781